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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/192,800	02/07/1994	TETSUJI SUDOH	15870150FWCI	2124
22850	7590	06/08/2006	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.			MCGARRY, SEAN	
1940 DUKE STREET			ART UNIT	
ALEXANDRIA, VA 22314			PAPER NUMBER	

1635

DATE MAILED: 06/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

08/192,800

Applicant(s)

SUDOH ET AL.

Examiner

Sean R. McGarry

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2006.
- 2a) ☒ This action is **FINAL**.      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 36,37 and 62-73 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 36 and 37 is/are allowed.
- 6) ☒ Claim(s) 62-73 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

This action is in response to the petition decision of 7/26/05. The petition decision withdraws the abandonment action of 7/26/05. The finality of the action mailed 6/2/04 is withdrawn and this final action is now made of record.

Claims 36, 37, and 62-73 are pending and under examination.

Claims 36 and 37 remain allowed.

Applicant's arguments with respect to new claims 62-73 have been considered but are moot in view of the new ground(s) of rejection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 62-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seilhamer et al [US 5,674,710], Seilhamer et al [US 5,948,761], and Seilhamer et al [US 5,114,923].

Seilhamer et al '710 discloses the recited peptides of the invention in claims 1-8, columns 4-5 and 9, and SEQ ID NOS: 44-46. At column 17 it is stated. "The peptide compounds may be formulated into the compositions as neutral or salt forms.

Pharmaceutically acceptable nontoxic salts include the acid addition salts (formed with the free amino groups) and which are formed with inorganic acids such as, for example, hydrochloric or phosphoric acids, or organic acids such as, for example, hydrochloric or phosphoric acids, or such organic acids as acetic, oxalic, tartaric, mandelic, and the like."

Seilhamer et al '761 disclose the recited peptides of the invention in claims 1-7, columns 4-5 and 9-10, and within SEQ ID NOS: 44-46. At column 18 it is stated. "The peptide compounds may be formulated into the compositions as neutral or salt forms. Pharmaceutically acceptable nontoxic salts include the acid addition salts (formed with the free amino groups) and which are formed with inorganic acids such as, for example, hydrochloric or phosphoric acids, or organic acids such as, for example, hydrochloric or phosphoric acids, or such organic acids as acetic, oxalic, tartaric, mandelic, and the like."

Seilhamer et al '923 disclose the recited peptides at columns 4-5 and 10 and in claims 1-4. Claim 4 recites specifically the peptide of instant claim 65, for example. At column 19 it is stated. "The peptide compounds may be formulated into the compositions as neutral or salt forms. Pharmaceutically acceptable nontoxic salts include the acid addition salts (formed with the free amino groups) and which are formed with inorganic acids such as, for example, hydrochloric or phosphoric acids, or

organic acids such as, for example, hydrochloric or phosphoric acids, or such organic acids as acetic, oxalic, tartaric, mandelic, and the like.”

All of the Seilhamer patents have therefore taught the peptides recited in the claims and have taught the use of inorganic and organic acids to formulate the peptides of their invention into salt compositions for medicinal preparations. Seilhamer et al have taught the use of acid salts in general and provide specific examples of acids that may be used. The Seilhamer et al patents do not specifically teach the specifically recited acids recited in the instant claims. However it is the position of the examiner that the selection of the a specific organic acid was clearly a routine matter of choice at the time of invention. It is noted that Seilhamer et al disclose that “organic acids” can be used to produce a salt composition and then provide a number of examples including acetic acid and tartaric acids. The instant claims now recite organic acids that are equivalent of those suggested by Seilhamer and are clearly within the scope of the teachings of Seilhamer et al. It is noted that the instant specification appears to admit that the use of organic acids in the preparation of salt compositions was routine at the time of invention, For example, it is stated at page 10 of the instant specification “The peptide of formula (I) of the present invention can be converted into an acid addition salt according to a **conventional manner** using an inorganic acid such as hydrochloric acid, sulfuric acid, phosphoric acid, or the like; or an organic acid such as formic acid, acetic acid, citric acid, tartaric acid, fumaric acid, maleic acid, or the like” (emphasis added).

The invention as a whole would therefore have been *prima facie* obvious to one in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R. McGarry whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Sean R McGarry  
Primary Examiner  
Art Unit 1635